Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

Clinical practice guideline: hoarseness (dysphonia) (update).

Bibliographic Source(s)

Stachler RJ, Francis DO, Schwartz SR, Damask CC, Digoy GP, Krouse HJ, McCoy SJ, Ouellette DR, Patel RR, Reavis CCW, Smith LJ, Smith M, Strode SW, Woo P, Nnacheta LC. Clinical practice guideline: hoarseness (dysphonia) (update). Otolaryngol Head Neck Surg. 2018 Mar;158(1_suppl):S1-S42. [470 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Schwartz S, Cohen S, Dailey S, Rosenfeld R, Deutsch E, Gillespie B, Granieri E, Hapner E, Kimball E, Krouse H, McMurray S, Medina S, O'Brien K, Ouellette D, Messinger-Rapport B, Stachler R, Strode S, Thompson D, Stemple J, Willging P, Cowley T, McCoy, Bernad P, Patel M. Clinical practice guideline: hoarseness (dysphonia). Otolaryngol Head Neck Surg. 2009 Sep;141(3S2):S1-S31. [21 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

NEATS Assessment

National Guideline Clearinghouse (NGC) has assessed this guideline's adherence to standards of trustworthiness, derived from the Institute of Medicine's report Clinical Practice Guidelines We Can Trust.

= Poor = Fair = Good = Very Good = Excellent

Assessment	Standard of Trustworthiness
YES	Disclosure of Guideline Funding Source
	Disclosure and Management of Financial Conflict of Interests

	Guideline Development Group Composition
YES	Multidisciplinary Group
YES	Methodologist Involvement
▮▮▮▮▯	Patient and Public Perspectives
	Use of a Systematic Review of Evidence
▮▮▮▮▮	Search Strategy
▮▮▮▮▯	Study Selection
▮▮▮▯▯	Synthesis of Evidence
	Evidence Foundations for and Rating Strength of Recommendations
▮▮▮▮▮	Grading the Quality or Strength of Evidence
▮▮▮▮▮	Benefits and Harms of Recommendations
▮▮▮▮▮	Evidence Summary Supporting Recommendations
▮▮▮▮▮	Rating the Strength of Recommendations
▮▮▮▮▮	Specific and Unambiguous Articulation of Recommendations
▮▮▮▯▯	External Review
▮▮▮▮▮	Updating

Recommendations

Major Recommendations

The evidence grades (A-D, X) and evidence-based statements (Strong Recommendation, Recommendation and Option,) are defined at the end of the "Major Recommendations" field.

Statement 1. Identification of Abnormal Voice

Clinicians should identify dysphonia in a patient with altered voice quality, pitch, loudness, or vocal effort that impairs communication or reduces quality of life (QOL).

Recommendation based on observational studies with a preponderance of benefit over harm.

Action Statement Profile: 1

> Quality improvement opportunity: To promote awareness of dysphonia by all clinicians as a condition that may require intervention or additional investigation. National Quality Strategy domain: Prevention and Treatment of Leading Causes of Morbidity and Mortality.
> Aggregate evidence quality: Grade C, observational studies for symptoms, with 1 systematic review of QOL in voice disorders and 2 systematic reviews on medication side effects

Level of confidence in evidence: High
Benefit: Timely recognition of the need to search for an underlying etiology; identify patients who may benefit from treatment; discourage the perception of dysphonia as a trivial condition that does not warrant attention
Risks, harms, costs: Potential anxiety related to diagnosis; time expended in diagnosis, documentation, and discussion
Benefits-harm assessment: Preponderance of benefits over harm
Value judgments: The group believes that this is a critical component to caring for patients with altered voice, but it was constrained from calling this a strong recommendation from a lack of A- or B-level evidence
Intentional vagueness: None
Role of patient preference: Small
Exclusions: None
Policy Level: Recommendation
Differences of opinions: None

Statement 2. Identifying Underlying Cause of Dysphonia

Clinicians should assess the patient with dysphonia by history and physical examination for underlying causes of dysphonia and factors that modify management.

Recommendation based on observational studies with a preponderance of benefit over harm.

Action Statement Profile: 2

Quality improvement opportunity: To guide the expediency and nature of recommended treatments/investigations through identification of potential underlying causes of the dysphonia.
National Quality Strategy domains: Prevention and Treatment of Leading Causes of Morbidity and Mortality; Effective Communication and Care Coordination.
Aggregate evidence quality: Grade C, observational studies
Level of confidence in evidence: High
Benefit: To identify potential causative factors of the dysphonia, increase awareness of underlying causes of dysphonia, identify patients at risk for serious underlying conditions, and identify underlying cause to allow for targeted treatment
Risks, harms, costs: None
Benefits-harm assessment: Preponderance of benefit over harm
Value judgments: Further management of dysphonia is completely dependent on the underlying cause. The group believed that while this seems obvious, it was an opportunity to educate clinicians about potential etiologies
Intentional vagueness: None
Role of patient preferences: Small
Exclusions: None
Policy level: Strong recommendation
Differences of opinions: None

Statement 3. Escalation of Care

Clinicians should assess the patient with dysphonia by history and physical examination to identify factors where expedited laryngeal evaluation is indicated. These include but are not limited to recent surgical procedures involving the head, neck, or chest; recent endotracheal intubation; presence of concomitant neck mass; respiratory distress or stridor; history of tobacco abuse; and whether the patient is a professional voice user.

Strong recommendation based on observational studies with a preponderance of benefit over harm.

Action Statement Profile: 3

Quality improvement opportunity: To encourage early referral of patients with dysphonia whose

history, symptoms, or physical examination is concerning for a serious underlying etiology. National Quality Strategy domains: Prevention and Treatment of Leading Causes of Morbidity and Mortality; Effective Communication and Care Coordination; Patient Safety.
Aggregate evidence quality: Grade B, based on overwhelmingly consistent evidence from observational studies
Level of confidence in evidence: High
Benefit: To identify factors early in the course of management that could influence the timing of diagnostic procedures, choice of interventions, or provision of follow-up care; to identify risk factors; to identify populations for whom early or more aggressive intervention may be warranted (i.e., professional voice)
Risks, harms, costs: Time in assessment
Benefits-harm assessment: Preponderance of benefit over harm
Value judgments: Importance of history taking and identifying modifying factors as an essential component of providing quality care
Intentional vagueness: The term *expedited* does not specify exact timing
Role of patient preferences: Moderate (small: in the setting of a neck mass with dysphonia or concern for malignancy)
Exclusions: None
Policy level: Strong recommendation
Differences of opinions: None

Statement 4A. Laryngoscopy and Dysphonia

Clinicians may perform diagnostic laryngoscopy at any time for a patient with dysphonia.

Option based on observational studies, expert opinion, and a balance of benefit and harm.

Action Statement Profile: 4A

Quality improvement opportunity: To highlight the important role of visualizing the larynx and vocal folds in treating a patient with dysphonia. National Quality Strategy domains: Prevention and Treatment of Leading Causes of Morbidity and Mortality; Effective Communication and Care Coordination; Patient Safety.
Aggregate evidence quality: Grade C, based on observational studies
Level of confidence in evidence: High
Benefit: Establishing the underlying diagnosis, possible reduction in cost, improved diagnostic accuracy, appropriate referrals and treatment, avoidance of missed or delayed diagnosis, reduced anxiety by establishing diagnosis
Risks, harms, costs: Patient discomfort, cost of examination, procedure-related morbidity
Benefits-harm assessment: Balance of benefit and harm
Value judgments: Laryngoscopy is an essential tool for diagnosing the cause of dysphonia and should be available to those who can perform it; however, dysphonia is often self-limited and may resolve spontaneously without a diagnosis
Intentional vagueness: None
Role of patient preferences: Moderate
Exclusions: None
Policy level: Option
Differences of opinions: None

Statement 4B. Need for Laryngoscopy in Persistent Dysphonia

Clinicians should perform laryngoscopy, or refer to a clinician who can perform laryngoscopy, when dysphonia fails to resolve or improve within 4 weeks or irrespective of duration if a serious underlying cause is suspected.

Recommendation based on observational studies, expert opinion, and a preponderance of benefit over harm.

Action Statement Profile: 4B

Quality improvement opportunity: To highlight the important role of visualizing the larynx and vocal folds in treating a patient with dysphonia, especially if the dysphonia fails to improve within 4 weeks' onset. National Quality Strategy domains: Prevention and Treatment of Leading Causes of Morbidity and Mortality; Effective Communication and Care Coordination.
Aggregate evidence quality: Grade C, observational studies on the natural history of benign laryngeal disorders; grade C for observational studies plus expert opinion on defining what constitutes a serious underlying condition
Level of confidence in evidence: High
Benefit: Avoid missed or delayed diagnosis of serious conditions among patients without additional signs and/or symptoms to suggest underlying disease; permit prompt assessment of the larynx when serious concern exists
Risks, harms, costs: Potential for delay in diagnosis; procedure-related morbidity; procedure-related expense; patient discomfort
Benefits-harm assessment: Preponderance of benefit over harm
Value judgments: A need exists to balance timely diagnostic intervention with the potential for overutilization and excessive cost. The guideline update panel debated the optimal time for assessment of the larynx with a consensus-based approach and agreed on 4 weeks with the option to proceed more promptly based on clinical circumstances
Intentional vagueness: The term *serious underlying* concern is subject to the discretion of the clinician. Some conditions are clearly serious, but for other patients, the seriousness of the condition is dependent on the patient. Intentional vagueness was incorporated to allow for clinical judgment in the expediency of evaluation
Role of patient preferences: If there is a serious underlying concern, then there is a limited role for patient preference; however, among patients without a serious underlying concern, the role for patient preference is moderate
Exclusions: None
Policy level: Recommendation
Differences of opinions: There was some disagreement about whether the time frame should be 4 or 6 weeks. After casting their votes, 10 panel members favored a 4-week time frame, and 5 favored a 6-week time frame.

Statement 5. Imaging

Clinicians should not obtain computed tomography (CT) or magnetic resonance imaging (MRI) among patients with a primary voice complaint prior to visualization of the larynx.

Recommendation against imaging based on observational studies of harm, absence of evidence concerning benefit, and a preponderance of harm over benefit.

Action Statement Profile: 5

Quality improvement opportunity: To reduce variations of care and unnecessary expense as well as harm from radiation and/or contrast exposure. National Quality Strategy domain: Making Quality Care More Affordable.
Aggregate evidence quality: Grade C, observational studies regarding the adverse events of CT and MRI; no evidence identified concerning benefits among patients with dysphonia before laryngoscopy
Level of confidence in evidence: High
Benefit: Avoid unnecessary testing and overdiagnosis; minimize cost and adverse events; maximize the diagnostic yield of CT and MRI when indicated; avoid radiation
Risks, harms, costs: Potential for delayed/missed diagnosis
Benefits-harm assessment: Preponderance of benefit over harm
Value judgments: None
Intentional vagueness: None
Role of patient preferences: Small

Exclusions: None
Policy level: Recommendation against
Differences of opinions: None

Statement 6. Antireflux Medication and Dysphonia

Clinicians should not prescribe antireflux medications to treat isolated dysphonia, based on symptoms alone attributed to suspected gastroesophageal reflux disease (GERD) or laryngopharyngeal reflux (LPR), without visualization of the larynx.

Recommendation against prescribing based on randomized trials with limitations and observational studies with a preponderance of harm over benefit.

Action Statement Profile: 6

Quality improvement opportunity: To limit widespread use of antireflux medications as empiric therapy for dysphonia without symptoms of GERD or seeing changes in the larynx associated with LPR or laryngitis, given limited evidence of benefit and the potential adverse effects of the medications. National Quality Strategy domains: Prevention and Treatment of Leading Causes of Morbidity and Mortality; Patient Safety; Making Quality Care More Affordable.
Aggregate evidence quality: Grade B, randomized trials with limitations showing lack of benefits for antireflux therapy among patients with laryngeal symptoms alone, including dysphonia; observational studies with inconsistent or inconclusive results; inconclusive evidence regarding the prevalence of dysphonia as the only manifestation of reflux disease
Level of confidence in evidence: Medium based on small inconsistent randomized trials with heterogeneous entry criteria and poorly defined outcome measures
Benefit: Avoidance of unnecessary therapy; reduced cost; avoidance of complications from proton pump inhibitors (PPIs); avoidance of diagnostic and treatment delay due to course of PPI therapy.
Risks, harms, costs: Potential withholding of therapy from patients who may benefit
Benefits-harm assessment: Preponderance of benefit over harm
Value judgments: The committee thought that there is general overuse of these medications and that they have limited usefulness for most patients with dysphonia but that there may be a role for antireflux medications in a subset of hard-to-define cases. They also recognize that there is a role for these medications to treat gastroesophageal reflux
Intentional vagueness: None
Role of patient preferences: Small
Exclusions: None
Policy level: Recommendation against
Differences of opinions: The panel was divided about whether to include the terms *GERD* and *LPR* in the action statement or to leave it simply as symptoms alone. The majority favored inclusion of these terms in the KAS

Statement 7. Corticosteroid therapy

Clinicians should not routinely prescribe corticosteroids for patients with dysphonia prior to visualization of the larynx.

Recommendation against prescribing based on randomized trials showing adverse events and absence of clinical trials demonstrating benefits with a preponderance of harm over benefit for steroid use.

Action Statement Profile: 7

Quality improvement opportunity: To discourage the empiric use of steroids for dysphonia prior to laryngeal examination. National Quality Strategy domains: Prevention and Treatment of Leading Causes of Morbidity and Mortality; Patient Safety; Making Quality Care More Affordable.
Aggregate evidence quality: Grade B, randomized trials showing increased incidence of adverse events associated with orally administered steroids; absence of clinical trials demonstrating any benefit of steroid treatment on outcomes

Level of confidence in evidence: High
Benefit: Avoid potential adverse events associated with unproven therapy
Risks, harms, costs: None
Benefits-harm assessment: Preponderance of harm over benefit for steroid use
Value judgments: Avoid adverse events of ineffective or unproven therapy
Intentional vagueness: The word *routine* is used to acknowledge that there may be specific situations, based on laryngoscopy results, or other associated conditions that may justify steroid use on an individualized basis
Role of patient preferences: Small; there is a role for shared decision making in weighing the harms of steroids against the potential yet unproven benefit in specific circumstances (i.e., professional or avocation voice use and acute laryngitis)
Exclusions: Children with croup
Policy level: Recommendation against
Differences of opinions: None

Statement 8. Antimicrobial Therapy

Clinicians should not routinely prescribe antibiotics to treat dysphonia.

Strong recommendation against prescribing based on systematic reviews and randomized trials showing ineffectiveness of antibiotic therapy and a preponderance of harm over benefit.

Action Statement Profile: 8

Quality improvement opportunity: To discourage the misuse of antibiotics. National Quality Strategy domains: Prevention and Treatment of Leading Causes of Morbidity and Mortality; Patient Safety; Making Quality Care More Affordable.
Aggregate evidence quality: Grade A, systematic reviews showing no benefit for antibiotics for acute laryngitis or upper respiratory tract infection; grade A evidence showing potential harms of antibiotic therapy
Level of confidence in evidence: High
Benefit: Avoidance of ineffective therapy, unnecessary cost, and antibiotic resistance
Risks, harms, costs: Potential for failing to treat bacterial, fungal, or mycobacterial causes of dysphonia
Benefits-harm assessment: Preponderance of harm over benefit if antibiotics are prescribed
Value judgments: Importance of limiting antimicrobial therapy to treating bacterial or fungal infections
Intentional vagueness: The word *routine* is used in the KAS to discourage empiric therapy yet to acknowledge there are occasional circumstances where antimicrobial use may be appropriate
Role of patient preferences: None
Exclusions: Patients with dysphonia caused by bacterial, fungal, or mycobacterial infection
Policy level: Strong recommendation against
Differences of opinions: None

Statement 9A. Laryngoscopy Prior to Voice Therapy

Clinicians should perform diagnostic laryngoscopy, or refer to a clinician who can perform diagnostic laryngoscopy, before prescribing voice therapy and document/communicate the results to the speech-language pathologist (SLP).

Recommendation based on observational studies showing benefit and a preponderance of benefit over harm.

Action Statement Profile: 9A

Quality improvement opportunity: To encourage the routine use of diagnostic laryngoscopy for patients with dysphonia (hoarseness) before initiation of voice therapy and to promote the most effective treatment practices for patients with dysphonia. National Quality Strategy domains:

Effective Communication and Care Coordination; Prevention and Treatment of Leading Causes of Morbidity and Mortality.
Aggregate evidence quality: Grade C, observational studies of the benefit of laryngoscopy for voice therapy
Level of confidence in evidence: High
Benefit: Avoid delay in diagnosing laryngeal conditions not treatable with voice therapy, optimize voice therapy by allowing targeted therapy
Risks, harms, costs: Delay in initiation of voice therapy; cost of the laryngoscopy and associated clinician visit; patient discomfort
Benefits-harm assessment: Preponderance of benefit over harm
Value judgments: To ensure no delay in identifying pathology not treatable with voice therapy. The SLP should not initiate therapy prior to laryngoscopy
Intentional vagueness: None
Role of patient preferences: Small
Exclusions: None
Policy level: Recommendation
Differences of opinions: None

Statement 9B. Advocating for Voice Therapy

Clinicians should advocate voice therapy for patients with dysphonia from a cause amenable to voice therapy.

Strong recommendation based on systematic reviews and randomized trials with a preponderance of benefit over harm.

Action Statement Profile: 9B

Quality improvement opportunity: To promote effective communication with patients and to promote the most effective prevention and treatment practices for patients with dysphonia. National Quality Strategy domains: Person and Family Centered Care; Prevention and Treatment of Leading Causes of Morbidity and Mortality; Making Quality Care More Affordable.
Aggregate evidence quality: Grade A, RCTs and systematic reviews
Level of confidence in evidence: High
Benefit: Improve voice-related QOL; prevent relapse; potentially prevent need for more invasive therapy
Risks, harms, costs: No harm reported in controlled trials; cost of treatment
Benefits-harm assessment: Preponderance of benefit over harm
Value judgments: Voice therapy is underutilized in managing dysphonia despite efficacy; advocacy is needed
Intentional vagueness: Deciding which patients will benefit from voice therapy is often determined by the voice therapist (SLP)
Role of patient preferences: Small
Exclusions: Patients unable to participate in therapy
Policy level: Strong recommendation
Differences of opinions: None

Statement 10. Surgery

Clinicians should advocate for surgery as a therapeutic option for patients with dysphonia with conditions amenable to surgical intervention, such as suspected malignancy, symptomatic benign vocal fold lesions that do not respond to conservative management, or glottic insufficiency.

Recommendation based on observational studies demonstrating a benefit of surgery in these conditions and a preponderance of benefit over harm.

Action Statement Profile: 10

Quality improvement opportunity: To advocate that clinicians discuss and consider surgery as a therapeutic option for patients with dysphonia whose underlying etiology is amenable to surgical intervention. National Quality Strategy domains: Person and Family Centered Care; Prevention and Treatment of Leading Causes of Morbidity and Mortality.
Aggregate evidence quality: Grade B, in support of surgery to reduce dysphonia and improve voice quality among selected patients based on observational studies overwhelmingly demonstrating the benefit of surgery
Level of confidence in evidence: High
Benefit: Potential for improved voice outcomes among carefully selected patients
Risks, harms, costs: None
Benefits-harm assessment: Preponderance of benefit over harm
Value judgments: Surgical options for treating dysphonia are not always recognized
Intentional vagueness: None
Role of patient preferences: Small
Exclusions: None
Policy level: Recommendation
Differences of opinions: None

Statement 11. Botulinum Toxin

Clinicians should offer, or refer to someone who can offer, botulinum toxin injections for the treatment of dysphonia caused by SD and other types of laryngeal dystonia.

Recommendation based on RCTs with minor limitations and preponderance of benefit over harm.

Action Statement Profile: 11

Quality improvement opportunity: To expedite referral for suspected SD. National Quality Strategy domains: Person and Family Centered Care; Prevention and Treatment of Leading Causes of Morbidity and Mortality.
Aggregate evidence quality: Grade B, few controlled trials, diagnostic studies with minor limitations, and overwhelmingly consistent evidence from observational studies
Level of confidence in evidence: High
Benefit: Improved voice quality and voice-related QOL
Risks, harms, costs: Dysphagia, airway obstruction, breathy voice, direct costs of treatment, time off work, and indirect costs of repeated treatments
Benefits-harm assessment: Preponderance of benefit over harm
Value judgments: Botulinum toxin is beneficial despite the potential need for repeated treatments given the limited availability of other effective interventions for SD
Intentional vagueness: None
Role of patient preferences: Large
Exclusions: Allergy to botulinum toxin
Policy level: Recommendation
Differences of opinions: None

Statement 12. Education/Prevention

Clinicians should inform patients with dysphonia about control/preventive measures.

Recommendation based on observational studies, small-sample RCTs, expert opinion, and a preponderance of benefit over harm.

Action Statement Profile: 12

Quality improvement opportunity: To provide guidance to clinicians in educating patients on behavioral strategies and environmental measures that may prevent or decrease the risk of dysphonia. National Quality Strategy domains: Person and Family Centered Care; Prevention and Treatment of Leading Causes of Morbidity and Mortality.

Aggregate evidence quality: Grade C, evidence based on observational studies, small-sample RCTs, expert opinion, and a preponderance of benefit over harm
Level of confidence in evidence: High
Benefit: Possible decreased risk of recurrence of dysphonia; improved vocal hygiene may reduce dysphonia; possible prevention of dysphonia for persons at high risk
Risks, harms, costs: Time of education; cost of potentially ineffective interventions
Benefits-harm assessment: Preponderance of benefit over harm
Value judgments: None
Intentional vagueness: None
Role of patient preferences: Small role in terms of receiving information from clinician; moderate to large role in shared decision making that involves choosing specific preventive and control measures to use
Exclusions: None
Policy level: Recommendation
Differences of opinions: None

Statement 13. Outcomes

Clinicians should document resolution, improvement, or worsened symptoms of dysphonia or change in QOL among patients with dysphonia after treatment or observation.

Recommendation based on randomized trials and cohort studies with a preponderance of benefit over harm.

Action Statement Profile: 13

Quality improvement opportunity: To ensure that patients with dysphonia are followed until the dysphonia has improved or resolved or the underlying condition has been diagnosed and appropriately managed. National Quality Strategy domain: Effective Communication and Care Coordination.
Aggregate evidence quality: Grade C, recommendation based on randomized trials and cohort studies with a preponderance of benefit over harm
Level of confidence in evidence: High
Benefit: Document the final status of dysphonia, communicate with referring clinicians, document favorable outcomes or failures of treatment
Risks, harms, costs: Cost of follow-up visits
Benefits-harm assessment: Preponderance of benefit over harm
Value judgments: None
Intentional vagueness: The time frame for assessing outcome is not stated
Role of patient preferences: Small
Exclusions: None
Policy level: Recommendation
Differences of opinions: None

Definitions

Aggregate Grades of Evidence by Question Type[a]

Grade	CEBM Level	Treatment	Harm	Diagnosis	Prognosis
A	1	Systematic review[b] of randomized trials	Systematic review[b] of randomized trials, nested case-control studies, or observational studies with dramatic effect	Systematic review[b] of cross-sectional studies with consistently applied reference standard and blinding	Systematic review[b] of inception cohort studies[c]

Grade	CEBM Level	Treatment	Harm	Diagnosis	Prognosis
B	2	Randomized trials or observational studies with dramatic effects or highly consistent evidence	Randomized trials or observational studies with dramatic effects or highly consistent evidence	Cross-sectional studies with consistently applied reference standard and blinding	Inception cohort studies[c]
C	3-4	Nonrandomized or historically controlled studies, including case-control and observational studies	Nonrandomized controlled cohort or follow-up study (postmarketing surveillance) with sufficient numbers to rule out a common harm; case series, case-control, or historically controlled studies	Nonconsecutive studies, case-control studies, or studies with poor, nonindependent, or inconsistently applied reference standards	Cohort study, control arm of a randomized trial, case series, or case-control studies; poor-quality prognostic cohort study
D	5	Case reports, mechanism-based reasoning, or reasoning from first principles			
X	N/A	Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm			

Abbreviation: CEBM, Oxford Centre for Evidence-Based Medicine; N/A, not applicable

[a]Adapted from Howick J, Chalmers I, Glasziou; the OCEBM Levels of Evidence Working Group. The Oxford 2011 levels of evidence: Oxford Centre for Evidence-Based Medicine. http://www.cebm.net/index.aspx?o=5653 . Accessed October 22, 2015.

[b]A systematic review may be downgraded to level B because of study limitations, heterogeneity, or imprecision.

[c]A group of individuals identified for subsequent study at an early, uniform point in the course of the specified health condition or before the condition develops.

Guideline Definitions for Evidence-Based Statements

Statement	Definition	Implication
Strong Recommendation	A strong recommendation means that the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits, in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (grade A or B).[a] In some clearly identified circumstances, strong recommendations may be made on the basis of lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation means that the benefits exceed the harms (or that the harms exceed the benefits, in the case of a negative recommendation) but that the quality of evidence is not as strong (grade B or C).[a] In some clearly identified circumstances, recommendations may be made on the basis of lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Clinicians should also generally follow a recommendation but should remain alert to new information and sensitive or patient preferences.
Option	An option means either that the quality of evidence that exists is suspect (grade D)[a] or that well-done studies (grade A, B, or C) a show little clear advantage to one approach versus another.	Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives. Patient preference should have a substantial influencing role.

[a]American Academy of Pediatrics classification scheme.

Clinical Algorithm(s)

An algorithm titled "Hoarseness (dysphonia) clinical practice guideline algorithm" is provided in the original guideline document.

Scope

Disease/Condition(s)

Dysphonia

Note: Dysphonia is characterized by altered vocal quality, pitch, loudness, or vocal effort that impairs communication and/or quality of life.

Guideline Category

Diagnosis

Evaluation

Management

Prevention

Treatment

Clinical Specialty

Family Practice

Internal Medicine

Otolaryngology

Pediatrics

Speech-Language Pathology

Surgery

Intended Users

Advanced Practice Nurses

Physician Assistants

Physicians

Respiratory Care Practitioners

Speech-Language Pathologists

Guideline Objective(s)

- To provide evidence-based recommendations on treating patients who present with dysphonia
- To improve the quality of care for patients with dysphonia, based on current best evidence

Target Population

All individuals presenting with dysphonia, regardless of age

Interventions and Practices Considered

1. Identification
2. History and physical examination
3. Referral to specialty care
4. Laryngoscopy
5. Voice therapy
6. Surgery
7. Botulinum toxin (Botox)
8. Education/prevention
9. Documentation

Note: The following interventions were considered but not recommended: computed tomography (CT), magnetic resonance imaging (MRI), antireflux medications, routine corticosteroids, routine use of antibiotics.

Major Outcomes Considered

- Change in quality of life (QOL)
- Complications and adverse events
- Economic consequences
- Adherence to therapy
- Absenteeism
- Communication function
- Voice-related health care utilization

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search

An information specialist conducted 3 literature searches from December 2015 through April 2016 using a validated filter strategy to identify CPGs, systematic reviews, and RCTs. The search terms used were as follows: ("hoarseness"[MeSH Terms] OR "hoarseness"[tw] OR "hoarse"[tw] OR "aphonia"[MeSH Terms] OR "aphonia"[tw] OR "phonation disorder"[tw] OR "dysphonia"[MeSH Terms] OR "dysphonia"[tw] OR "phonation disorders"[tw] OR "voice disorder"[tw] OR "voice disorders"[tw] OR "vocal disorder"[tw] OR "vocal disorders"[tw] OR laryngitis[tw] OR "laryngeal disorder"[tw] OR "laryngeal disorders"[tw]). These search terms were used to capture all evidence on the population by incorporating all relevant treatments and outcomes.

The English-language searches were performed in multiple databases: Health Services/Technology Assessment Texts (HSTAT), Agency for Healthcare Research and Quality (AHRQ), BIOSIS Previews, CAB Abstracts, Allied and Complementary Medicine Database (AMED), EMBASE, Guidelines International Network (GIN) International Guideline Library, Cochrane Library (Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects (DARE), Health Technology Assessment (HTA)

Database, NNHS Economic Evaluation Database National Health Service Economic Evaluation Database (NHS EED), Australian National Health and Medical Research Council, New Zealand Guidelines Group, Scottish Intercollegiate Guidelines Network (SIGN), TRIP Database, Canadian Medical Association (CMA) Infobase, National Guideline Clearinghouse, PubMed Search, and CINAHL.

The initial English-language search identified 106 clinical practice guidelines (CPGs), 561 systematic reviews, and 516 randomized controlled trials (RCTs) published in 2008 or later. CPGs were included if they met quality criteria of (1) an explicit scope and purpose, (2) multidisciplinary stakeholder involvement, (3) systematic literature review, (4) explicit system for ranking evidence, and (5) explicit system for linking evidence to recommendations. Systematic reviews were emphasized and included if they met quality criteria of (1) a clear objective and methodology, (2) an explicit search strategy, and (3) valid data extraction methods. RCTs were included if they met quality criteria as follows: (1) trials involved study randomization; (2) trials were described as double-blind; and (3) trials denoted a clear description of withdrawals and dropouts of study participants. After removal of duplicates, irrelevant references, and non–English language articles, 6 CPGs, 55 systematic reviews, and 24 RCTs were retained. In certain instances, targeted searches were performed by guideline update group (GUG) members to address gaps from the systematic searches identified in writing the guideline from June 2016 through February 2017.

Number of Source Documents

In total, the evidence supporting the guideline includes 3 clinical practice guidelines (CPGs), 16 systematic reviews, and 4 randomized controlled trials (RCTs).

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Aggregate Grades of Evidence by Question Type[a]

Grade	CEBM Level	Treatment	Harm	Diagnosis	Prognosis
A	1	Systematic review[b] of randomized trials	Systematic review[b] of randomized trials, nested case-control studies, or observational studies with dramatic effect	Systematic review[b] of cross-sectional studies with consistently applied reference standard and blinding	Systematic review[b] of inception cohort studies[c]
B	2	Randomized trials or observational studies with dramatic effects or highly consistent evidence	Randomized trials or observational studies with dramatic effects or highly consistent evidence	Cross-sectional studies with consistently applied reference standard and blinding	Inception cohort studies[c]
C	3-4	Nonrandomized or historically controlled studies, including case-control and	Nonrandomized controlled cohort or follow-up study (postmarketing surveillance) with sufficient numbers to rule out a common harm; case series,	Nonconsecutive studies, case-control studies, or studies with poor, nonindependent, or inconsistently	Cohort study, control arm of a randomized trial, case series, or case-control studies; poor-

Grade	CEBM Level	Treatment	Harm	Diagnosis	Prognosis
		observational studies	case-control, or historically controlled studies	applied reference standards	quality prognostic cohort study
D	5	Case reports, mechanism-based reasoning, or reasoning from first principles			
X	N/A	Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm			

Abbreviation: CEBM, Oxford Centre for Evidence-Based Medicine; N/A, not applicable

[a]Adapted from Howick J, Chalmers I, Glasziou; the OCEBM Levels of Evidence Working Group. The Oxford 2011 levels of evidence: Oxford Centre for Evidence-Based Medicine. http://www.cebm.net/index.aspx?o=5653 . Accessed October 22, 2015.

[b]A systematic review may be downgraded to level B because of study limitations, heterogeneity, or imprecision.

[c]A group of individuals identified for subsequent study at an early, uniform point in the course of the specified health condition or before the condition develops.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The evidence-based approach to guideline development requires that the evidence supporting a policy be identified, appraised, and summarized and that an explicit link between evidence and statements be defined. Evidence-based statements reflect both the quality of evidence and the balance of benefit and harm that is anticipated when the statement is followed. The definitions for evidence-based statements are listed in the "Rating Scheme for the Strength of Evidence" and "Rating Scheme for the Strength of the Recommendations" fields.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) assembled a guideline update group (GUG) representing the disciplines of advanced practice nursing, bronchoesophagology, consumer advocacy, family medicine, geriatric medicine, internal medicine, laryngology, neurology, otolaryngology–head and neck surgery, pediatrics, professional voice, pulmonology, and speech-language pathology. The GUG had several conference calls and 1 in-person meeting during which it defined the scope and objectives of updating the guideline, reviewed comments from the expert panel review for each key action statement (KAS), identified other quality improvement opportunities, reviewed the literature search results, and drafted the document.

The evidence profile for each statement in the earlier guideline was then converted into an expanded action statement profile for consistency with the current development standards. Information was added to the action statement profiles regarding quality improvement opportunities, level of confidence in the evidence, differences of opinion, role of patient preferences, and any exclusion to which the action statement does not apply. New KASs were developed with an explicit and transparent a priori protocol for creating actionable statements based on supporting evidence and the associated balance of benefit and harm. Electronic decision support software (BRIDGE-Wiz; Yale Center for Medical Informatics, New Haven, Connecticut) was used to facilitate the creation of actionable recommendations and evidence profiles.

The updated guideline underwent GuideLine Implementability Appraisal to appraise adherence to methodologic standards, to improve clarity of recommendations, and to predict potential obstacles to implementation. The GUG received summary appraisals and modified an advanced draft of the guideline based on the appraisal.

Rating Scheme for the Strength of the Recommendations

Guideline Definitions for Evidence-Based Statements

Statement	Definition	Implication
Strong Recommendation	A strong recommendation means that the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits, in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (grade A or B).[a] In some clearly identified circumstances, strong recommendations may be made on the basis of lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation means that the benefits exceed the harms (or that the harms exceed the benefits, in the case of a negative recommendation) but that the quality of evidence is not as strong (grade B or C).[a] In some clearly identified circumstances, recommendations may be made on the basis of lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Clinicians should also generally follow a recommendation but should remain alert to new information and sensitive or patient preferences.
Option	An option means either that the quality of evidence that exists is suspect (grade D)[a] or that well-done studies (grade A, B, or C) a show little clear advantage to one approach versus another.	Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives. Patient preference should have a substantial influencing role.

[a]American Academy of Pediatrics classification scheme.

Cost Analysis

The guideline developers reviewed published cost analyses.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The updated guideline underwent GuideLine Implementability Appraisal to appraise adherence to methodologic standards, to improve clarity of recommendations, and to predict potential obstacles to implementation. The guideline update group (GUG) received summary appraisals and modified an

advanced draft of the guideline based on the appraisal. The final draft of the updated clinical practice guideline (CPG) was revised per the comments received during multidisciplinary peer review, open public comment, and journal editorial peer review.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate evaluation and management of dysphonia by improving diagnostic accuracy; reducing inappropriate antibiotic use, steroid use, anti-reflux medications, radiographic imaging; and promoting appropriate use of laryngoscopy, voice therapy, and surgery

For benefits of specific interventions considered in the guideline, see the "Major Recommendations" field.

Potential Harms

- In one study, adverse effects included mild breathiness (25%) and coughing on fluids (10%) for the patients with adductor spasmodic dysphonia (SD) and "mild stridor" for the patients with abductor SD. Many other studies documented similar rates of adverse effects (breathiness and dysphagia, choking on fluids). Postinjection dysphagia may be more common among patients with preexisting dysphagia. Exertional wheezing, exercise intolerance, and stridor were more commonly reported for patients with abductor SD. Adverse events may result from diffusion of drug from the target muscle to adjacent muscles ("black box warning" by the FDA). Adjusting the dose, distribution, and timing of injections may decrease the frequency of adverse events. Bleeding is rare, and vocal fold edema was documented for only 1 patient receiving saline as a placebo. Reports of sensations of burning, tickling, irritation of the larynx or throat, excessive thick secretions, and dryness also occurred. Systemic effects are rare, with only 2 reports of generalized botulism-like syndromes and 1 report of possible precipitation of biliary colic. Acquired resistance to botulinum toxin can occur.
- Refer to Table 8 in the original guideline document for side effects of corticosteroids.

For harms associated with specific interventions considered in the guideline, see the "Major Recommendations" field.

Contraindications

Contraindications

The use of polytetrafluoroethylene as a permanent injectable implant is not recommended due to its association with foreign body granulomas that can result in voice deterioration and airway compromise.

Qualifying Statements

Qualifying Statements

- This clinical practice guideline (CPG) is not intended as an exhaustive source of guidance for managing dysphonia (hoarseness). Rather, it is designed to assist clinicians by providing an evidence-based framework for decision-making strategies. The guideline is not intended to replace clinical judgment or establish a protocol for all individuals with this condition and may not provide the only appropriate approach to diagnosing and managing this program of care. As medical knowledge expands and technology advances, clinical indicators and guidelines are promoted as conditional and provisional proposals of what is recommended under specific conditions, but they are not absolute. Guidelines are not mandates. These do not and should not purport to be a legal standard of care. The responsible physician, in light of all circumstances presented by the individual patient, must determine the appropriate treatment. Adherence to these guidelines will not ensure successful patient outcomes in every situation. The American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) emphasizes that these clinical guidelines should not be deemed to include all proper treatment decisions or methods of care or to exclude other treatment decisions or methods of care reasonably directed to obtaining the same results.
- Guidelines are not intended to supersede professional judgment but rather may be viewed as a relative constraint on individual clinician discretion in a particular clinical circumstance. Less frequent variation in practice is expected for a "strong recommendation" as compared with a "recommendation." "Options" offer the most opportunity for practice variability. Clinicians should always act and decide in a way that they believe will best serve their patients' interests and needs, regardless of guideline recommendations. They must also operate within their scope of practice and according to their training. Guidelines represent the best judgment of a team of experienced clinicians and methodologists addressing the scientific evidence for a particular topic. Making recommendations about health practices involves value judgments on the desirability of various outcomes associated with management options. Values applied by the guideline panel sought to minimize harm and diminish unnecessary and inappropriate therapy. A major goal of the panel was to be transparent and explicit about how values were applied and to document the process.

Implementation of the Guideline

Description of Implementation Strategy

Implementation Considerations

The complete guideline is published as a supplement to *Otolaryngology–Head and Neck Surgery* to facilitate reference and distribution. The guideline was presented to American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNS) members as a miniseminar at the AAO-HNSF 2017 Annual Meeting & OTO Experience prior to publication. Existing brochures and publications by the AAO-HNSF will be updated to reflect the guideline recommendations. A fulltext version of the guideline will also be accessible free of charge at www.entnet.org .

An anticipated barrier to diagnosis is distinguishing modifying factors for dysphonia in a busy clinical setting. This barrier may be mitigated through a laminated teaching card or visual aid summarizing important factors that modify management.

Laryngoscopy is an option at any time for patients with dysphonia, but the guideline also recommends that no patient be allowed to wait >4 weeks prior to having his or her larynx examined. It is also clearly recommended that if there is a concern of an underlying serious condition, then laryngoscopy should be immediate. Tables in this guideline regarding causes for concern should help guide clinicians regarding

when prompt laryngoscopy is warranted. The cost of the laryngoscopy and the possible wait times to see clinicians trained in the technique may hinder access to care.

While the guideline acknowledges that there may be a significant role for antireflux therapy to treat laryngeal inflammation, empiric use of antireflux medications for dysphonia has minimal support and a growing list of potential risks. Avoidance of empiric use of antireflux therapy represents a significant change in practice for some clinicians. Educational pamphlets describing the risks and benefits of these medications may help facilitate this potential change in practice pattern.

Lack of knowledge about voice therapy by practitioners is a likely barrier to advocacy for its use. This barrier can be overcome by educational materials about voice therapy and its indications.

Implementation Tools

Clinical Algorithm

Mobile Device Resources

Patient Resources

Pocket Guide/Reference Cards

Quick Reference Guides/Physician Guides

Slide Presentation

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Stachler RJ, Francis DO, Schwartz SR, Damask CC, Digoy GP, Krouse HJ, McCoy SJ, Ouellette DR, Patel RR, Reavis CCW, Smith LJ, Smith M, Strode SW, Woo P, Nnacheta LC. Clinical practice guideline: hoarseness (dysphonia) (update). Otolaryngol Head Neck Surg. 2018 Mar;158(1_suppl):S1-S42. [470

references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

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2018 Mar

Guideline Developer(s)

American Academy of Otolaryngology - Head and Neck Surgery Foundation - Medical Specialty Society

Source(s) of Funding

American Academy of Otolaryngology—Head and Neck Surgery Foundation

Guideline Committee

American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNS) Guideline Update Group

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Financial Disclosures/Conflicts of Interest

Financial Disclosure and Conflicts of Interest

The cost of developing this guideline, including travel expenses of all panel members, was covered in full by the American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF). Potential conflicts of interest for all panel members in the past 2 years were compiled and distributed before the first conference call. After review and discussion of these disclosures, the panel concluded that individuals with potential conflicts could remain on the panel if they (1) reminded the panel of potential conflicts before any related discussion, (2) recused themselves from a related discussion if asked by the panel, and (3) agreed not to discuss any aspect of the guideline with industry before publication. Last, panelists were reminded that conflicts of interest extend beyond financial relationships and may include

personal experiences, how a participant earns a living, and the participant's previously established "stake" in an issue.

Disclosures

Competing interests: David O. Francis, research funding from the Patient Centered Outcomes Research Institute and National Institute on Deafness and Other Communication Disorders; Seth R. Schwartz, conference travel expenses for Cochlear Americas, Oticon Medical, and Cochlear Corporation (2013); Cecelia C. Damask, consulting fee from Audigy Medical, honoraria from Teva Respiratory, and webinar speaker for ALK; Helene J. Krouse, Society of Otorhinolaryngology and Head-Neck Nurses Research Award (principal investigator, no salary support), AAO-HNSF and Society of Otorhinolaryngology and Head-Neck Nurses editorial boards, and AAO-HNSF editor in chief (self and partner); Daniel R. Ouellette, principal investigator for clinical trial with Cardeas Pharmaceuticals, which examines the treatment of ventilator-associated pneumonia in the intensive care unit with inhaled amikacin/fosfomycin versus placebo; expert witness for law firm of Marynell Maloney for a case involving pulmonary embolism; chair, guideline oversight committee for American College of Chest Physicians; Rita R. Patel, American Speech- Language-Hearing Association Special Interest Group 3 coordinator; Charles (Charlie) W. Reavis, National Spasmodic Dysphonia Association board member and president; Libby J. Smith, Olympus product focus group; Steven W. Strode, American Academy of Family Physicians, federal-level lobbying; Lorraine C. Nnacheta, salaried employee, AAO-HNSF.

Sponsorships: AAO-HNSF.

Guideline Endorser(s)

American Academy of Otolaryngic Allergy - Medical Specialty Society

American Academy of Pediatrics - Medical Specialty Society

American Academy of Physical Medicine and Rehabilitation - Medical Specialty Society

American Broncho-Esophagological Association - Medical Specialty Society

American College of Chest Physicians - Medical Specialty Society

American Laryngological Association - Medical Specialty Society

American Society of Pediatric Otolaryngology - Medical Specialty Society

American Speech-Language-Hearing Association - Professional Association

National Association of Teachers of Singing - Nonprofit Organization

National Spasmodic Dysphonia Association - Nonprofit Organization

Society of Otorhinolaryngology and Head and Neck Nurses - Medical Specialty Society

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Schwartz S, Cohen S, Dailey S, Rosenfeld R, Deutsch E, Gillespie B, Granieri E, Hapner E, Kimball E, Krouse H, McMurray S, Medina S, O'Brien K, Ouellette D, Messinger-Rapport B, Stachler R, Strode S, Thompson D, Stemple J, Willging P, Cowley T, McCoy, Bernad P, Patel M. Clinical practice guideline: hoarseness (dysphonia). Otolaryngol Head Neck Surg. 2009 Sep;141(3S2):S1-S31. [21 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the SAGE Journals Web site.

Availability of Companion Documents

The following are available:

- Stachler RJ, Francis DO, Schwartz SR, Damask CC, Digoy GP, Krouse HJ, McCoy SJ, Ouellette DR, Patel RR, Reavis CCW, Smith LJ, Smith M, Strode SW, Woo P, Nnacheta LC. Clinical practice guideline: hoarseness (dysphonia) (update) executive summary. Otolaryngol Head Neck Surg. 2018 Mar;158(3):409-426. Available from the SAGE Journals Web site.
- Clinical practice guideline: hoarseness (dysphonia) (update). Podcast part 1 and 2. Alexandria (VA): American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF); 2018 Mar. Available from the American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF) Web site.
- Clinical practice guideline: hoarseness (dysphonia) (update). Pocket guide and mobile app. Alexandria (VA): American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF); 2018 Mar. Available from the AAO-HNSF Web site.
- Rosenfeld RM, Shiffman RN, Robertson P. Clinical practice guideline development manual, third edition: a quality-driven approach for translating evidence into action. Otolaryngol Head Neck Surg. 2013 Jan;148(Suppl 1):S1-55. Available from the SAGE Journals Web site.
- A variety of education opportunities are available from the AAO-HNSF Web site.

In addition, a slide set is available from the AAO-HNSF by contacting Sarah O'Connor (soconnor@entnet.org).

Patient Resources

A variety of resources for patients are available from the American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF) Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

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